Liza M. Walsh
Christine I. Gannon
Selina M. Ellis
CONNELL FOLEY LLP
One Newark Center
1085 Raymond Boulevard, 19th Floor
Newark, NJ 07102
(973) 757-1100

Of Counsel:
Natalie C. Clayton (admitted *pro hac vice*)
Alston & Bird LLP
90 Park Avenue, 15th Floor
New York, NY 10016
(212) 210-9400

Matthew W. Howell (admitted *pro hac vice*)
Alston & Bird LLP
One Atlantic Center
1201 West Peachtree Street
Atlanta, GA 30309
(404) 881-7000

Attorneys for Defendant Actavis Laboratories FL, Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MALLINCKRODT LLC, MALLINCKRODT INC. AND DEPOMED, INC., *Plaintiffs,* v. ACTAVIS LABORATORIES FL, INC., *Defendant.*	Civil Action No. 2:15-cv-03800-KSH-CLW **AMENDED ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Actavis Laboratories FL, Inc. (formerly known as Watson Laboratories, Inc.-Florida) ("Actavis" or "Defendant") hereby answers the Amended Complaint of Plaintiffs Mallinckrodt

LLC, Mallinckrodt Inc. (collectively, “Mallinckrodt”), and Depomed Inc. (“Depomed”) (together with Mallinckrodt, collectively “Plaintiffs”).

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Actavis filing an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market generic versions of Plaintiffs’ pharmaceutical product XARTEMIS™ XR prior to the expiration of United States Patent Nos. 8,597,681 (“the ’681 patent”); 8,658,631 (“the ’631 patent”); 8,741,885 (“the ’885 patent”); 8,980,319 (“the ’319 patent”); 8,992,975 (“the ’975 patent”); 7,976,870 (“the ’870 patent”); 8,668,929 (“the ’929 patent”); 8,372,432 (“the ‘432 patent”); 8,377,453 (“the ‘453 patent”); 8,394,408 (“the ‘408 patent”); and 9,050,335 (“the ‘335 patent”).

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that this action purports to arise under Title 35 of the United States Code. To the extent an answer is required, Actavis admits that it filed an Abbreviated New Drug Application with the United States Food and Drug Administration seeking approval to market oxycodone hydrochloride and acetaminophen extended release tablets prior to the expiration of the ’681, ’631, ’885, ’319, ’975, ’870, ’929, ‘432, ‘453, ‘408, and ‘335 patents.

PARTIES

2. Plaintiff Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

ANSWER: Actavis lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 2, and on that basis denies them.

3. Plaintiff Mallinckrodt Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

ANSWER: Actavis lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 3, and on that basis denies them.

4. Plaintiff Depomed, Inc. ("Depomed") is a corporation organized and existing under the laws of the State of California, having a place of business at 7999 Gateway Blvd., Suite 300, Newark, CA 94560.

ANSWER: Actavis lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 4, and on that basis denies them.

5. On information and belief, Defendant Actavis Laboratories FL, Inc., is a company organized and existing under the laws of the State of Florida with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis is in the business of selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

ANSWER: Actavis admits that Actavis is a company organized and existing under the laws of the State of Florida. Actavis denies that Actavis has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway Parsippany, NJ 07054. Actavis' principal place of business is located at 4955 Orange Drive, Fort Lauderdale, FL 33314. Actavis denies the remaining allegations of Paragraph 6 of the Amended Complaint.

6. On information and belief, Actavis has previously submitted to the jurisdiction of this Court and has purposefully availed itself of the jurisdiction of this Court by filing lawsuits and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis does not contest personal jurisdiction for purposes of this action only. Actavis denies the remaining allegations in Paragraph 6 of the Amended Complaint.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the Court has subject matter jurisdiction over the claims asserted against Defendant pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Actavis by virtue of, *inter alia*, it having corporate presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of New Jersey.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis does not contest personal jurisdiction for purposes of this action only. Actavis denies the remaining allegations in Paragraph 8 of the Amended Complaint.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis does not contest that venue is proper in this Court for purposes of this action only. Actavis denies the remaining allegations in Paragraph 9 of the Amended Complaint.

XARTEMIS XR

10. XARTEMIS™ XR is an extended release tablet for oral administration. XARTEMIS™ XR contains the active ingredients oxycodone hydrochloride and acetaminophen. The recommended dose of XARTEMIS™ XR is one dose every 12 hours without regard to patients' fed state. XARTEMIS™ XR is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate.

ANSWER: Actavis admits that the label for XARTEMIS™ XR states that it is an "extended-release tablet for oral administration." Actavis admits that the XARTEMIS XR label states that it contains the active ingredients acetaminophen and oxycodone hydrochloride. Actavis admits that the XARTEMIS XR label states that its recommended dose is "2 tablets every 12 hours without regard to food." Actavis admits that the XARTEMIS XR label states that it "is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate." Actavis denies the remaining allegations in Paragraph 10 of the Amended Complaint.

> 11. XARTEMIS™ XR combines an opioid analgesic agent with a non-opioid analgesic agent. XARTEMIS™ XR provides the advantage of additive and synergistic analgesic effects allowing for a lower dose of opioid, fewer side effects, and the ability to treat a broader spectrum of pain or pain states due to the different mechanisms of actions.

ANSWER: Actavis admits that the XARTEMIS XR label states that it contains the active ingredients acetaminophen and oxycodone hydrochloride. Actavis lacks knowledge and information sufficient to form a belief about the truth of the remainder of the allegations in Paragraph 11, and therefore denies each and every remaining allegation in Paragraph 11 of the Amended Complaint on that basis.

> 12. Previously marketed drug products delivered the combination drugs as an immediate release product.

ANSWER: Actavis admits that previously marketed drug products, *i.e.*, prior art to the '681, '631, '885, '319, '975, '870, '929, '432, '453, '408, and '335 patents, delivered a combination of the active ingredients acetaminophen and oxycodone. Actavis lacks knowledge and information sufficient to form a belief about the truth of the remainder of the allegations in Paragraph 12, and on that basis denies them.

13. This limitation required the drug product to be administered frequently and/or continuously throughout the day (or night) for continuous pain management. This frequent and/or continuous dosing is often inconvenient and difficult to maintain. Regular dosing is, therefore, inconvenient and frequently leads to poor patient compliance – potentially resulting in a dose being taken after pain breaks through, causing unnecessary pain and suffering.

ANSWER: Actavis admits that previously marketed drug products, *i.e.*, prior art to the ’681, ’631, ’885, ’319, ’975, ’870, ’929, ‘432, ‘453, ‘408, and ‘335 patents, delivered a combination of the active ingredients acetaminophen and oxycodone. Actavis lacks knowledge and information sufficient to form a belief about the truth of the remainder of the allegations in Paragraph 13, and on that basis denies them.

14. During drug development, it was surprisingly discovered that a pharmaceutically acceptable gastric retentive dosage form can be formulated to provide release in the stomach of a combination of a sparingly soluble drug and a highly soluble drug at rates proportional to one another over an extended period of time.

ANSWER: Actavis lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 14, and on that basis denies them.

15. In 2008, Mallinckrodt licensed from Depomed patents, a patent application, and know-how and subsequent to completion of drug product development Mallinckrodt sought approval from the FDA to market XARTEMIS™ XR in the United States. The FDA approved Mallinckrodt’s New Drug Application No. 204031 (“the XARTEMIS™ XR NDA”) for oxycodone hydrochloride and acetaminophen extended-release tablets, under the trade name XARTEMIS™ XR, on March 11, 2014.

ANSWER: Actavis admits that the Orange Book lists NDA No. 204031 for XARTEMIS XR as being approved on March 11, 2014, and that the label for XARTEMIS XR states that it is an “extended-release tablet for oral administration.” Actavis lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 15, and on that basis denies them.

> 16. As a part of the regulatory process for obtaining approval of the XARTEMIS™ XR NDA, Mallinckrodt was required by the FDA to submit a proposed label for the drug. *See* 21 C.F.R. § 201.56(b). The label for XARTEMIS™ XR instructs physicians and patients, *inter alia*, about the proper dosage and administration of XARTEMIS™ XR.

ANSWER: This paragraph contains legal conclusions for which no response is required. To the extent a response is required, Actavis admits that the FDA requires submission of proposed labels for drug products. Actavis lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 16, and on that basis denies them.

> 17. The label for XARTEMIS™ XR indicates, *inter alia*, that one dose of XARTEMIS™ XR is recommended twice daily.

ANSWER: Actavis admits that the label for XARTEMIS XR states that "The recommended dose of XARTEMIS XR is 2 tablets every 12 hours without regard to food." Actavis denies the remaining allegations of Paragraph 17.

> 18. A physician familiar with the use of extended-release tablets for the management of acute pain such as XARTEMIS™ XR would therefore understand that administration of an opioid analgesic combined with a non-opioid analgesic agent would be subject to the label's instruction to administer a dose twice daily.

ANSWER: Actavis lacks knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 18, and on that basis, denies them.

> 19. Plaintiffs have educated prescribing physicians regarding the use of XARTEMIS™ XR. Physicians are informed that the recommended dose of XARTEMIS™ XR is one dose every 12 hours. Physicians are told that the second dose may be administered as early as 8 hours after the initial dose if patients require analgesia at that time. Subsequent doses are to be administered every 12 hours. Further, on information and belief, it is the standard of care for physicians to treat acute pain in a manner that prevents pain break through. One or more claims of the patents in suit cover the method of treating pain by administering oxycodone hydrochloride and acetaminophen extended-release every 8-12 hours or twice daily.

ANSWER: Actavis lacks knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 19, and on that basis, denies them.

THE PATENTS-IN-SUIT

20. On December 3, 2013, the United States Patent and Trademark Office issued the ’681 patent, entitled “Methods of producing stabilized solid dosage pharmaceutical compositions containing morphinans.” The ’681 patent was assigned to Mallinckrodt by inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal K. Gupta, and Stephen Overholt. A copy of the ’681 patent is attached hereto as Exhibit A.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’681 patent states that it was issued on December 3, 2013, and that it is titled “Methods of producing stabilized solid dosage pharmaceutical compositions containing morphinans.” Actavis admits that, per the face of the patent, the ’681 patent purports to have been assigned to Mallinckrodt by its alleged inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal K. Gupta, and Stephen Overholt. Actavis admits that what purports to be a true and correct copy of the ’681 patent was attached to the Amended Complaint as Exhibit A. Actavis denies the remaining allegations of Paragraph 20.

21. On February 25, 2014, the United States Patent and Trademark Office issued the ’631 patent, entitled “Combination composition comprising oxycodone and acetaminophen for rapid onset and extended duration of analgesia.” The ’631 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the ’631 patent is attached hereto as Exhibit B.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’631 patent states that it was issued on February 25, 2014, and that it is titled “Combination composition comprising oxycodone and acetaminophen for rapid onset and extended duration of analgesia.” Actavis admits that, per the face of the patent, the ’631 patent purports to have been assigned to Mallinckrodt by its alleged inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. Actavis admits that what purports to be a true and correct copy of the ’631 patent was attached to the Amended Complaint as Exhibit B. Actavis denies the remaining allegations of Paragraph 21.

> 22. On June 3, 2014, the United States Patent and Trademark Office issued the ’885 patent, entitled “Gastric retentive extended release pharmaceutical compositions.” The ’885 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the ’885 patent is attached hereto as Exhibit C.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’885 patent states that it was issued on June 3, 2014, and that it is titled “Gastric retentive extended release pharmaceutical compositions.” Actavis admits that, per the face of the patent, the ’885 patent purports to have been assigned to Mallinckrodt by its alleged inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. Actavis admits that what purports to be a true and correct copy of the ’885 patent was attached to the Amended Complaint as Exhibit C. Actavis denies the remaining allegations of Paragraph 22.

> 23. On March 17, 2015, the United States Patent and Trademark Office issued the ’319 patent, entitled “Methods of producing stabilized solid dosage pharmaceutical composition containing morphinans.” The ’319 patent was assigned to Mallinckrodt by inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal Gupta, and Stephen Overholt. A copy of the ’319 patent is attached hereto as Exhibit D.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’319 patent states that it was issued on March 17, 2015, and that it is titled “Methods of producing stabilized solid dosage pharmaceutical composition containing morphinans.” Actavis admits that, per the face of the patent, the ’319 patent purports to have been assigned to Mallinckrodt by its alleged inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal Gupta, and Stephen Overholt. Actavis admits that what purports to be a true and correct copy of the ’319 patent was attached to the Amended Complaint as Exhibit D. Actavis denies the remaining allegations of Paragraph 23.

24. On December 3, 2013, the United States Patent and Trademark Office issued the ’975 patent, entitled “Methods of producing stabilized solid dosage pharmaceutical compositions containing morphinans.” The ’975 patent was assigned to Mallinckrodt by inventors Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal K. Gupta, and Stephen Overholt. A copy of the ’975 patent is attached hereto as Exhibit E.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis denies that the face of the ’975 patent states that it was issued on December 3, 2013, and that it is titled “Methods of producing stabilized solid dosage pharmaceutical compositions containing morphinans.” Actavis admits that, per the face of the patent, the ’975 patent purports to have been assigned to Mallinckrodt. Actavis denies that the alleged inventors of the ‘975 patent are Jae Han Park, Tiffani Eisenhauer, Anish Dhanarajan, Vishal K. Gupta, and Stephen Overholt. Actavis admits that what purports to be a true and correct copy of the ’975 patent was attached to the Amended Complaint as Exhibit E. Actavis denies the remaining allegations of Paragraph 24.

25. On July 12, 2011, the United States Patent and Trademark Office issued the ’870 patent, entitled “Gastric retentive oral dosage form with restricted drug release in the lower gastrointestinal tract.” The ’870 patent was assigned to Depomed, Inc. by inventors Bret Berner, John W. Shell, and Jenny Louie-Helm. Depomed, Inc. granted Mallinckrodt an exclusive license under the ’870 patent with respect to, *inter alia*, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ’870 patent is attached hereto as Exhibit F.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’870 patent states that it was issued on July 12, 2011, and that it is titled “Gastric retentive oral dosage form with restricted drug release in the lower gastrointestinal tract." Actavis admits that, per the face of the patent, the'870 patent purports to have been assigned to Depomed, Inc. by its alleged inventors Bret Berner, John W. Shell, and Jenny Louie-Helm. Actavis admits that what purports to be a true and correct copy of the '870 patent was attached to the Amended Complaint as Exhibit F. Actavis is without information or belief regarding the remaining allegations of Paragraph 25, and on that basis, denies them.

> 26. On March 11, 2014, the United States Patent and Trademark Office issued the '929 patent, entitled "Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic." The '929 patent was assigned to Depomed, Inc. by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the '929 patent with respect to, *inter alia*, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the '929 patent is attached hereto as Exhibit G.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the '929 patent states that it was issued on March 11, 2014, and that it is titled "Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic." Actavis admits that, per the face of the patent, the '929 patent purports to have been assigned to Depomed, Inc. by its alleged inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Actavis admits that what purports to be a true and correct copy of the '929 patent was attached to the Amended Complaint as Exhibit G. Actavis is without information or belief regarding the remaining allegations of Paragraph 26, and on that basis, denies them.

> 27. On February 12, 2013, the United States Patent and Trademark Office issued the '432 patent, entitled "Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic." The '432 patent was assigned to Depomed by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the '432 patent with respect to, *inter alia*, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the '432 patent is attached hereto as Exhibit H.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’432 patent states that it was issued on February 12, 2013, and that it is titled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” Actavis admits that, per the face of the patent, the ’432 patent purports to have been assigned to Depomed, Inc. by its alleged inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Actavis admits that what purports to be a true and correct copy of the ’432 patent was attached to the Amended Complaint as Exhibit H. Actavis is without information or belief regarding the remaining allegations of Paragraph 27, and on that basis, denies them.

28. On February 19, 2013, the United States Patent and Trademark Office issued the ‘453 patent, entitled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” The ‘453 patent was assigned to Depomed by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the ‘453 patent with respect to, *inter alia*, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ‘453 patent is attached hereto as Exhibit I.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’453 patent states that it was issued on February 19, 2013, and that it is titled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” Actavis admits that, per the face of the patent, the ’453 patent purports to have been assigned to Depomed, Inc. by its alleged inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Actavis admits that what purports to be a true and correct copy of the ’453 patent was attached to the Amended Complaint as Exhibit I. Actavis is without information or belief regarding the remaining allegations of Paragraph 28, and on that basis, denies them.

29. March 12, 2013, the United States Patent and Trademark Office issued the ‘408 patent, entitled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” The ‘408 patent was assigned to Depomed by inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Depomed granted Mallinckrodt an exclusive license under the ‘408 patent with respect to, *inter alia*, oxycodone hydrochloride and acetaminophen extended release products known as XARTEMIS™ XR. A copy of the ‘408 patent is attached hereto as Exhibit J.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’408 patent states that it was issued on March 12, 2013, and that it is titled “Gastric retentive extended-release dosage forms comprising combinations of a non-opioid analgesic and an opioid analgesic.” Actavis admits that, per the face of the patent, the ’408 patent purports to have been assigned to Depomed, Inc. by its alleged inventors Chien-Hsuan Han, Sui Yuen Eddie Hou, and Monica L. Reid. Actavis admits that what purports to be a true and correct copy of the ’408 patent was attached to the Amended Complaint as Exhibit J. Actavis is without information or belief regarding the remaining allegations of Paragraph 29, and on that basis, denies them.

30. On June 9, 2015, the United States Patent and Trademark Office issued the ‘335 patent, entitled “Pharmaceutical compositions for extended release of oxycodone and acetaminophen resulting in a quick onset and prolonged period of analgesia.” The ‘335 patent was assigned to Mallinckrodt by inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. A copy of the ‘335 patent is attached hereto as Exhibit K.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Actavis admits that the face of the ’335 patent states that it was issued on June 9, 2015, and that it is titled “Pharmaceutical compositions for extended release of oxycodone and acetaminophen resulting in a quick onset and prolonged period of analgesia.” Actavis admits that, per the face of the patent, the ’335 patent purports to have been assigned to Mallinckrodt by its alleged inventors Krishna Devarakonda, Michael J. Guiliani, Vishal K. Gupta, Ralph A. Heasley, and Susan Shelby. Actavis admits that what purports to be a true and correct copy of the ’335 patent was attached to the Amended Complaint as Exhibit K. Actavis is without information or belief regarding the remaining allegations of Paragraph 30, and on that basis, denies them.

31. Each of the foregoing patents are listed for XARTEMIS™ XR in the Patent and Exclusivity Information Addendum of the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”). The Patent Use Codes listed in the Orange Book for the XARTEMIS™ XR product are “Method of Treating Patients with Gastric Retentive Dosage Form” and “Management of Acute Pain in Patients Requiring Opioid Analgesia.”

ANSWER: Actavis admits that the ’681, ’631, ’885, ’319, ’975, ’870, ’929, ‘432, ‘453, ‘408, and ‘335 patents are listed in the Orange Book in connection with XARTEMIS XR. Actavis admits that the Orange Book contains two Patent Use Codes, “Method of Treating Patients with Gastric Retentive Dosage Form” and “Management of Acute Pain in Patients Requiring Opioid Analgesia.” Actavis denies that a Patent Use Code is listed in the Orange Book for each asserted patent. Actavis denies the remaining allegations of Paragraph 31.

ACTAVIS’S ANDA

32. On information and belief, Actavis submitted ANDA No. 207113 (“the Actavis ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market oxycodone hydrochloride and acetaminophen extended-release tablets before the expiration of the patents in suit. The oxycodone hydrochloride and acetaminophen extended-release tablets described in the Actavis ANDA are herein referred to as the “Actavis Product.”

ANSWER: Actavis admits that Actavis submitted ANDA No. 207113 to the FDA seeking FDA approval to commercially manufacture, use, offer for sale, and sell the products that are the subject of that ANDA, and that Actavis was seeking approval of its ANDA before the expiration of the patents-in-suit. Actavis denies the remaining allegations in Paragraph 32 of the Amended Complaint.

33. The Actavis ANDA refers to and relies upon the XARTEMIS™ XR NDA and contains data that, according to Actavis, demonstrates the bioequivalence of the Actavis Product and XARTEMIS™ XR.

ANSWER: Actavis admits that ANDA No. 207113 refers to the XARTEMIS XR NDA and contains data that demonstrates the bioequivalence of the oxycodone hydrochloride and acetaminophen extended-release tablets described in ANDA No. 207113 ("Actavis Product") and XARTEMIS XR. Actavis denies the remaining allegations in Paragraph 33 of the Amended Complaint.

34. On or about April 24, 2015, Plaintiffs received Defendant' letter (the "Actavis Notification") stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents in suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product (the "Actavis Paragraph IV Certification"). On or about September 3, 2015, Actavis sent Defendants a second notice letter stating that Actavis had included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '335 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product.

ANSWER: Actavis admits that Actavis sent a letter to Plaintiffs on April 23, 2015, stating that Actavis had included a certification in ANDA No. 207113, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents in suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product. Actavis admits that Actavis sent a letter to Plaintiffs on September 3, 2015, stating that Actavis had included a certification in ANDA No. 207113, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '335 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis Product. Actavis denies the remaining allegations in Paragraph 34 of the Amended Complaint.

COUNT I
ACTAVIS'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,597,681 UNDER 35 U.S.C. § 271(e)(2)(A)

35. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-34 of this Complaint.

ANSWER: Actavis restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

36. Actavis has infringed the ’681 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’681 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’681 patent. Actavis denies that it has infringed the ’681 patent and denies the remaining allegations of Paragraph 36.

37. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’681 patent.

ANSWER: Denied.

38. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT II
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,658,631 UNDER 35 U.S.C. § 271(e)(2)(A)

39. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-38 of this Complaint.

ANSWER: Actavis restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

40. Actavis has infringed the ’631 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’631 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’631 patent. Actavis denies that it has infringed the ’631 patent and denies the remaining allegations of Paragraph 40.

41. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’631 patent.

ANSWER: Denied.

42. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT III
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,741,885 UNDER 35 U.S.C. § 271(e)(2)(A)

43. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-42 of this Complaint.

ANSWER: Actavis restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

44. Actavis has infringed the ’885 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’885 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’885 patent. Actavis denies that it has infringed the ’885 patent and denies the remaining allegations of Paragraph 44.

45. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’885 patent.

ANSWER: Denied.

46. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT IV
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,980,319 UNDER 35 U.S.C. § 271(e)(2)(A)

47. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-46 of this Complaint.

ANSWER: Actavis restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

48. Actavis has infringed the ’319 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’319 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’319 patent. Actavis denies that it has infringed the ’319 patent and denies the remaining allegations of Paragraph 48.

49. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’319 patent.

ANSWER: Denied.

50. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT V
ACTAVIS'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,992,975 UNDER 35 U.S.C. § 271(e)(2)(A)

51. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-50 of this Complaint.

ANSWER: Actavis restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

52. Actavis has infringed the '975 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '975 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the '975 patent. Actavis denies that it has infringed the '975 patent and denies the remaining allegations of Paragraph 52.

53. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '975 patent.

ANSWER: Denied.

54. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT VI
ACTAVIS'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,976,870 UNDER 35 U.S.C. § 271(e)(2)(A)

55. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-54 of this Complaint.

ANSWER: Actavis restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

56. Actavis has infringed the ’870 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’870 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’870 patent. Actavis denies that it has infringed the ’870 patent and denies the remaining allegations of Paragraph 56.

57. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’870 patent.

ANSWER: Denied.

58. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT VII
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,668,929 UNDER 35 U.S.C. § 271(e)(2)(A)

59. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-58 of this Complaint.

ANSWER: Actavis restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

60. Actavis has infringed the ’929 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’929 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’929 patent. Actavis denies that it has infringed the ’929 patent and denies the remaining allegations of Paragraph 60 of the Complaint.

61. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’929 patent.

ANSWER: Denied.

62. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT VIII
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,372,432 UNDER 35 U.S.C. § 271(e)(2)(A)

63. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-62 of this Complaint.

ANSWER: Actavis restates and incorporates its responses to the preceding paragraphs as if fully set forth herein.

64. Actavis has infringed the ’432 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’432 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’432 patent. Actavis denies that it has infringed the ’432 patent and denies the remaining allegations of Paragraph 64 of the Amended Complaint.

65. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’432 patent.

ANSWER: Denied.

66. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT IX
ACTAVIS’S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,377,453 UNDER 35 U.S.C. § 271(e)(2)(A)

67. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-66 of this Complaint.

ANSWER: Actavis restates and incorporates its responses to the preceding paragraphs as if fully set forth herein.

68. Actavis has infringed the ’453 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’453 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’453 patent. Actavis denies that it has infringed the ’453 patent and denies the remaining allegations of Paragraph 68 of the Amended Complaint.

69. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’453 patent.

ANSWER: Denied.

70. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT X
ACTAVIS'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,394,408 UNDER 35 U.S.C. § 271(e)(2)(A)

71. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-70 of this Complaint.

ANSWER: Actavis restates and incorporates its responses to the preceding paragraphs as if fully set forth herein.

72. Actavis has infringed the '408 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the '408 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the '408 patent. Actavis denies that it has infringed the '408 patent and denies the remaining allegations of Paragraph 72 of the Amended Complaint.

73. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '408 patent.

ANSWER: Denied.

74. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

COUNT XI
ACTAVIS'S DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,050,335 UNDER 35 U.S.C. § 271(e)(2)(A)

75. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-74 of this Complaint.

ANSWER: Actavis restates and incorporates its responses to the preceding paragraphs as if fully set forth herein.

76. Actavis has infringed the ’335 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Actavis ANDA, by which Actavis seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Actavis Product prior to the expiration of the ’335 patent.

ANSWER: Actavis admits that ANDA No. 207113 seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets prior to the expiration of the ’335 patent. Actavis denies that it has infringed the ’335 patent and denies the remaining allegations of Paragraph 76 of the Amended Complaint.

77. Plaintiffs will be substantially and irreparably harmed if Actavis is not enjoined from infringing the ’335 patent.

ANSWER: Denied.

78. Plaintiffs have no adequate remedy at law

ANSWER: Denied.

COUNT XII
EXCEPTIONAL CASE WITH RESPECT TO ACTAVIS UNDER 35 U.S.C. § 285

79. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-78 of this Complaint.

ANSWER: Actavis restates and incorporates its responses to the preceding paragraphs as if fully set forth herein.

80. Actavis alleges that eleven different patents duly examined by the U.S. Patent & Trademark Office are invalid or not infringed. This case is exceptional, and Plaintiffs should be granted award of attorneys’ fees under 35 U.S.C. § 285 in light of Actavis’s conduct.

ANSWER: Denied.

PRAYER FOR RELIEF

Actavis denies that Plaintiffs are entitled to the relief requested in Paragraphs A-Q of the Amended Complaint.

DEFENSES

Actavis sets forth the following affirmative and other defenses. Actavis does not intend by doing so to assume the burden of proof on those matters on which, under law, Plaintiffs bear the burden of proof.

FIRST DEFENSE- NONINFRINGEMENT OF U.S. PATENT NO. 8,597,681

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’681 patent.

SECOND DEFENSE- INVALIDITY OF U.S. PATENT NO. 8,597,681

One or more claims of the ’681 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

THIRD DEFENSE- NONINFRINGEMENT OF U.S. PATENT NO. 8,658,631

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’631 patent.

FOURTH DEFENSE- INVALIDITY OF U.S. PATENT NO. 8,658,631

One or more claims of the ’631 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

FIFTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,741,885

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’885 patent.

SIXTH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,741,885

One or more claims of the ’885 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

SEVENTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,980,319

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’319 patent.

EIGHTH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,980,319

One or more claims of the ’319 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

NINTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,992,975

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’975 patent.

TENTH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,992,975

One or more claims of the ’975 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States

Code.

ELEVENTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,976,870

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’870 patent.

TWELFTH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,976,870

One or more claims of the ’870 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

THIRTEENTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,668,929

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’929 patent.

FOURTEENTH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,668,929

One or more claims of the ’929 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

FIFTEENTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,372,432

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’432 patent.

SIXTEENTH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,372,432

One or more claims of the ’432 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

SEVENTEENTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,377,453

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’453 patent.

EIGHTEENTH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,377,453

One or more claims of the ‘453 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

NINETEENTH DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 8,394,408

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’408 patent.

TWENTIETH DEFENSE-
INVALIDITY OF U.S. PATENT NO. 8,394,408

One or more claims of the ’408 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

TWENTY-FIRST DEFENSE-
NONINFRINGEMENT OF U.S. PATENT NO. 9,050,335

Actavis does not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claim of the ’335 patent.

TWENTY-SECOND DEFENSE-
INVALIDITY OF U.S. PATENT NO. 9,050,335

One or more claims of the ’335 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

TWENTY-THIRD DEFENSE-
NO EXCEPTIONAL CASE

Actavis’ actions in defending this case do not give rise to an exceptional case under 35 U.S.C. §§ 271(e)(4) and 285.

TWENTY-FOURTH DEFENSE-
PRIOR USE UNDER 35 U.S.C. § 273

Actavis does not infringe the claims of the ’681, ’631, ’885, ’319, ’975, ’870, ’929, ‘432, ‘453, ‘408, and ‘335 patents to the extent that Plaintiffs read any such claim to cover any product that Actavis or its affiliates commercially used at least one year before the effective filing date of any of the patents-in-suit, or the date on which the claimed invention was disclosed to the public.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendant/Counterclaim-Plaintiff Actavis Laboratories FL, Inc. (formerly known as Watson Laboratories, Inc.-Florida) (“Actavis” or “Counterclaim-Plaintiff”) asserts the following Counterclaims against Plaintiffs/Counterclaim-Defendants Mallinckrodt LLC, Mallinckrodt Inc. (collectively, “Mallinckrodt”) and Depomed, Inc. (“Depomed”) (together with Mallinckrodt, “Plaintiffs” or “Counterclaim-Defendants”) for declaratory judgment of patent non-infringement and invalidity (or unenforceability), and allege as follows:

THE PARTIES

1. Actavis is a corporation organized under the laws of the State of Florida, having a

principle place of business at 4955 Orange Drive, Fort Lauderdale, FL 33314.

2. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

3. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Mallinckrodt Inc. is a corporation organized and existing under the laws of the state of Delaware, having a place of business at 675 McDonnell Boulevard, Hazelwood, Missouri 63042-2379.

4. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Depomed, Inc. is a corporation organized and existing under the laws of the State of California, having a place of business at Gateway Blvd., Suite 300, Newark, CA 94560.

JURISDICTION AND VENUE

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2202.

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Mallinckrodt LLC because Mallinckrodt LLC has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Actavis in this District, and/or because Mallinckrodt LLC conducts substantial business in this District.

8. This Court has personal jurisdiction over Mallinckrodt Inc. because Mallinckrodt Inc. has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Actavis in this District, and/or because Mallinckrodt Inc. conducts substantial

business in this District.

9. This Court has personal jurisdiction over Depomed, Inc. because Depomed, Inc. has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Actavis in this District, and/or because Depomed, Inc. conducts substantial business in this District.

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

FACTUAL BACKGROUND

11. On information and belief, and based on the FDA's website, Mallinckrodt Inc. is the current holder of New Drug Application ("NDA") No. 204031 for the manufacture and sale of XARTEMIS XR (oxycodone hydrochloride and acetaminophen) extended-release tablets.

12. On information and belief, Counterclaim-defendant Mallinckrodt markets oxycodone hydrochloride and acetaminophen extended-release tablets in the United States under the trade name XARTEMIS XR. According to the FDA website, XARTEMIS XR was approved by the FDA on March 11, 2014.

13. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Mallinckrodt is listed as the purported owner of record and purported assignee of U.S. Patent Nos. 7,976,681 ("the '681 patent"), 8,658,631 ("the '631 patent"), 8,741,885 ("the '885 patent"), 8,980,319 ("the '319 patent"), 8,992,975 ("the '975 patent"), and 9,050,335 ("the '335 patent").

14. On information and belief, and based on Plaintiffs' allegations, Counterclaim-defendant Depomed is listed as the purported owner and purported assignee of U.S. Patent Nos. 7,976,870 ("the '870 patent"), 8,668,929 ("the '929 patent"), 8,372,432 ("the '432 patent"), 8,377,453 ("the '453 patent"), and 8,394,408 ("the '408 patent").

15. Counterclaim-Defendants have informed the FDA of the unexpired '681, '631,

’885, ’319, ’975, ’870, ’929, ‘432, ‘453, ‘408, and ‘335 patents (collectively “the XARTEMIS XR Patents”) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use of sale of oxycodone hydrochloride and acetaminophen extended-release tablets. The XARTEMIS XR Patents are listed by the FDA in its publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book” for the NDA, under 21 U.S.C. § 355(j)(7).

16. Listing the XARTEMIS XR Patents in the Orange Book is a representation to the world that Counterclaim-Defendants believe these patents purportedly cover oxycodone hydrochloride and acetaminophen extended-release tablets, and that an infringement suit could be alleged against any generic ANDA applicant, including Counterclaim-Plaintiff, that attempts to seek approval for, and market, a generic version of oxycodone hydrochloride extended release tablets before the patents’ expiration.

17. Actavis currently holds Abbreviated New Drug Application (“ANDA”) No. 207113 oxycodone hydrochloride and acetaminophen extended-release tablets.

18. Actavis filed certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) certifying that each of the XARTEMIS XR Patents is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, importation, or sale of oxycodone hydrochloride and acetaminophen extended release tablets (“Proposed Product”) as covered by ANDA No. 207113. In accordance with 35 U.S.C. § 355(j)(2)(B)(i) and (ii), Actavis sent letters to Counterclaim-Defendants that provided notice of the Paragraph IV Certifications and provided the factual and legal bases for those Certifications.

19. In connection with the notice to Counterclaim-Defendants of Counterclaim-

Plaintiff's Paragraph IV Certification, Actavis provided an offer of confidential access to its ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc) and (III).

20. On June 5, 2015, Counterclaim-Defendants sued Counterclaim-Plaintiff in this district asserting infringement of the '681, '631, '885, '319, '975, '870, and '929 patents based on Actavis' filing of ANDA No. 207113 with a Paragraph IV certification. On November 2, 2015, Counterclaim-Defendants filed an amended complaint that, among other things, added allegations of infringement for the '432, '453, '408, and '335 patents. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Counterclaim-Plaintiff and Counterclaim-Defendants regarding the XARTEMIS XR Patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

21. Furthermore, based on, *inter alia*, the listing in the Orange Book of the XARTEMIS XR Patents; Actavis' filing of its ANDA with Paragraph IV Certifications to the XARTEMIS XR Patents; Actavis' intention to seek approval for its generic oxycodone hydrochloride and acetaminophen tablets before expiration of the XARTEMIS XR Patents; and Counterclaim-Defendants' suit against Counterclaim-Plaintiff for infringement of the XARTEMIS XR Patents there is a continuing case or controversy between Counterclaim-Plaintiff and Counterclaim-Defendants regarding infringement and validity of the XARTEMIS XR Patents.

22. The Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests with regard to whether Counterclaim-Plaintiff may market and sell generic oxycodone hydrochloride and acetaminophen tablets before expiration of the XARTEMIS XR Patents.

23. Thus, Counterclaim-Plaintiff is statutorily entitled to bring and maintain this action for declaratory judgment pursuant to the Medical Modernization Act in order to obtain

patent certainty, in accordance with 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

24. As a result of any exclusion of Counterclaim-Plaintiff from the marketplace, Counterclaim-Plaintiff and the public will be irreparably harmed by the potential indefinite delay in the market entry and availability of lower-priced oxycodone hydrochloride and acetaminophen extended-release tablets.

25. This case is exceptional pursuant to 35 U.S.C. § 285 and Counterclaim-Plaintiff is entitled to its reasonable attorney fees pursuant to that statute.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’681 PATENT

26. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

27. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’681 patent.

28. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’681 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’681 patent.

29. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen

extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’681 patent.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’631 PATENT

30. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

31. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’631 patent.

32. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’631 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’631 patent.

33. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’631 patent.

THIRD COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’885 PATENT

34. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

35. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’885 patent.

36. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’885 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’885 patent.

37. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’885 patent.

FOURTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’319 PATENT

38. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set

forth herein.

39. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’319 patent.

40. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’319 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’319 patent.

41. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’319 patent.

FIFTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’975 PATENT

42. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

43. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or

enforceable claim of the ’975 patent.

44. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’975 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’975 patent.

45. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’975 patent.

SIXTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’870 PATENT

46. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

47. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’870 patent.

48. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment

regarding the non-infringement of the ’870 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’870 patent.

49. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’870 patent.

SEVENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’929 PATENT

50. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

51. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’929 patent.

52. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’929 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’929 patent.

53. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture,

use, sale, offer for sale, and/or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’929 patent.

EIGHTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’432 PATENT

54. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

55. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’432 patent.

56. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’432 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’432 patent.

57. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’432 patent.

NINTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE '453 PATENT

58. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

59. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '453 patent.

60. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '453 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the '453 patent.

61. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '453 patent.

TENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE '408 PATENT

62. Counterclaim Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set

forth herein.

63. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’408 patent.

64. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’408 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’408 patent.

65. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’408 patent.

ELEVENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF THE ’335 PATENT

66. Counterclaim Plaintiffs re-assert, re-allege, and incorporate by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

67. The manufacture, use, sale, offer for sale, or importation of oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’335 patent.

68. Counterclaim-Plaintiff and Counterclaim-Defendants have adverse legal interests, and there is a substantial controversy between Counterclaim-Plaintiff and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the ’335 patent. Therefore, a present, genuine, and justiciable controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants regarding, *inter alia*, the infringement of any valid or enforceable claim of the ’335 patent.

69. Counterclaim-Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’335 patent.

TWELFTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’681 PATENT

70. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set

forth herein.

71. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’681 patent.

72. One or more claims of the ’681 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

73. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’681 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

74. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’681 patent are invalid.

THIRTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’631 PATENT

75. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

76. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’631 patent.

77. One or more claims of the ’631 patent are invalid for failure to comply with one

or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

78. As a direct and proximate result of Counterclaim-Defendants' assertion of the XARTEMIS XR Patents, which include the '631 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

79. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the '631 patent are invalid.

FOURTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '885 PATENT

80. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

81. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the '885 patent.

82. One or more claims of the '885 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

83. As a direct and proximate result of Counterclaim-Defendants' assertion of the XARTEMIS XR Patents, which include the '885 patent and also allegedly cover the oxycodone

hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

84. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’885 patent are invalid.

FIFTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’319 PATENT

85. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

86. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’319 patent.

87. One or more claims of the ’319 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

88. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’319 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and

substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

89. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’319 patent are invalid.

SIXTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’975 PATENT

90. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

91. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’975 patent.

92. One or more claims of the ’975 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

93. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’975 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

94. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’975 patent are invalid.

SEVENTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’870 PATENT

95. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

96. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’870 patent.

97. One or more claims of the ’870 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

98. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’870 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

99. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’870 patent are invalid.

EIGHTEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’929 PATENT

100. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

101. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’929 patent.

102. One or more claims of the ’929 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

103. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which include the ’929 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

104. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’929 patent are invalid.

NINETEENTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’432 PATENT

105. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

106. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’432 patent.

107. One or more claims of the ’432 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not

limited to §§ 101, 102, 103 and 112.

108. As a direct and proximate result of Counterclaim Defendants' assertion of the XARTEMIS XR Patents, which are related to the '432 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

109. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the '432 patent are invalid.

TWENTIETH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '453 PATENT

110. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

111. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the '453 patent.

112. One or more claims of the '453 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

113. As a direct and proximate result of Counterclaim-Defendants' assertion of the XARTEMIS XR Patents, which are related to the '453 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No.

207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

114. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’453 patent are invalid.

TWENTY-FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’408 PATENT

115. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

116. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’408 patent.

117. One or more claims of the ’408 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

118. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which are related to the ’408 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy

and reality to warrant the issuance of a declaratory judgment.

119. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’408 patent are invalid.

TWENTY-SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’335 PATENT

120. Counterclaim-Plaintiff re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Affirmative Defenses and Counterclaims, above, as if fully set forth herein.

121. An actual and justiciable case or controversy exists between Counterclaim-Plaintiff and Counterclaim-Defendants as to invalidity of the ’335 patent.

122. One or more claims of the ’335 patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 et seq., including but not limited to §§ 101, 102, 103 and/or 112.

123. As a direct and proximate result of Counterclaim-Defendants’ assertion of the XARTEMIS XR Patents, which are related to the ’335 patent and also allegedly cover the oxycodone hydrochloride and acetaminophen extended-release tablets covered by ANDA No. 207113, Counterclaim-Plaintiff has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

124. Counterclaim-Plaintiff is entitled to a judicial declaration that the claims of the ’335 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Actavis respectfully prays for judgment in its favor and against Plaintiffs Mallinckrodt and Depomed:

a. Dismissing with prejudice Plaintiffs' Amended Complaint against Actavis;

b. Denying Plaintiffs the relief requested in the Amended Complaint;

c. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '681 patent;

d. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '631 patent;

e. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '885 patent;

f. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '319 patent;

g. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’975 patent;

h. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’870 patent;

i. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’929 patent;

j. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’432 patent;

k. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’453 patent;

l. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’408 patent;

m. Declaring that the manufacture, use, sale, offer for sale, or importation of the oxycodone hydrochloride and acetaminophen extended-release tablets that are the subject of ANDA No. 207113 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’335 patent;

n. Declaring that the claims of the ’681 patent are invalid;

o. Declaring that the claims of the ’631 patent are invalid;

p. Declaring that the claims of the ’885 patent are invalid;

q. Declaring that the claims of the ’319 patent are invalid;

r. Declaring that the claims of the ’975 patent are invalid;

s. Declaring that the claims of the ’870 patent are invalid;

t. Declaring that the claims of the ’929 patent are invalid;

u. Declaring that the claims of the ’432 patent are invalid;

v. Declaring that the claims of the ’453 patent are invalid;

w. Declaring that the claims of the ’408 patent are invalid;

x. Declaring that the claims of the ’335 patent are invalid;

y. Declaring this case exceptional and awarding Actavis its reasonable attorneys’ fees and costs of these Counterclaims under 35 U.S.C. § 285; and

z. Awarding Actavis such other and further relief as the Court may deem just and proper.

Dated: November 17, 2015

CONNELL FOLEY LLP

By: *s/ Liza M. Walsh*
Liza M. Walsh
Christine I. Gannon
Selina M. Ellis
CONNELL FOLEY LLP
One Newark Center
1085 Raymond Boulevard, 19th Floor
Newark, NJ 07102
(973) 757-1100

Of Counsel:
Natalie C. Clayton (admitted *pro hac vice*)
Alston & Bird LLP
90 Park Avenue, 15th Floor
New York, NY 10016
(212) 210-9400

Matthew W. Howell (admitted *pro hac vice*)
Alston & Bird LLP
One Atlantic Center
1201 West Peachtree Street
Atlanta, GA 30309
(404) 881-7000

Attorneys for Defendant Actavis Laboratories FL, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 17, 2015

CONNELL FOLEY LLP

s/ *Liza M. Walsh*
Liza M. Walsh

3550165-1

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Counterclaim-Plaintiff hereby certifies that as a result of the nature of Counterclaim-Plaintiff's causes of action, as asserted in its counterclaims, this action is not appropriate for compulsory arbitration.

Dated: November 17, 2015

CONNELL FOLEY LLP

s/ *Liza M. Walsh*
Liza M. Walsh

CERTIFICATION OF SERVICE

I hereby certify that on November 17, 2015, the foregoing AMENDED ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS, was filed via CM/ECF with the Clerk of the Court and was thereby served on all counsel of record in this matter.

Dated: November 17, 2015

CONNELL FOLEY LLP

s/ *Liza M. Walsh*
Liza M. Walsh